

## 510 (k) Summary

**510(k) SUMMARY OF VASHE™ WOUND CLEANSER**

510 (k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.
Submitter	SteriloX Technologies, Inc. 320 King of Prussia Road Radnor, PA 19087
Contact Person	Howard Mann 320 King of Prussia Road Radnor, PA 19087 484-321-2703 610-341-0503 fax
Date Prepared	March 24 <sup>th</sup> , 2006
Trade Name	Vashe™
Common Name	Wound Cleanser
Classification Name	Solution, saline, (wound dressing)
Predicate Device	Allklenz™ Cleanser; Healthpoint Medical K965120, March 21 <sup>st</sup> 1997. CarraKlenz Wound Cleanser; Carrington Laboratories, Inc. K022670, Oct. 17th, 2002. Dermacyn™ Wound Cleanser, Oculus Innovative Sciences, K042729, September 30th, 2004 and Dermacyn™ Wound Dressing, Oculus Innovative Sciences, K041161, February 1st, 2005. Biopure™ MTAD™ Root Canal Cleanser, Dentsply International, K053167, December 8, 2005
Description	The subject device is a wound cleansing and disinfecting solution that is intended for cleansing, irrigating, debriding and disinfecting dermal wounds in addition to moistening and lubricating absorbent wound dressings. The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. Vashe is offered in various volumes.
Indications for Use	Vashe™ Wound Cleanser and Disinfectant is intended for cleansing, irrigating, moistening, debriding and disinfecting acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.
Substantial Equivalence	The product is similar in function and intended use to: <ul style="list-style-type: none"> <li>• Allklenz™ and CarraKlenz Wound Cleansers, manufactured by Healthpoint Medical and Carrington Laboratories, Inc. that include among their labeled uses the cleansing and irrigation of dermal wounds and removal of foreign material.</li> <li>• Dermacyn™ Wound Cleanser and Wound Dressing manufactured by Oculus Innovative Sciences, that include among it's labeled uses the cleansing, moistening and debriding of dermal wounds in addition to moistening and lubricating absorbent wound dressings.</li> <li>• Biopure™ MTAD™ Root Canal Cleanser manufactured by Dentsply International, that include among its labeled uses the cleaning and disinfecting of the root canal system.</li> </ul>
Non-clinical Performance	Pre-clinical testing demonstrated biocompatibility of the Vashe Wound Cleanser.
Conclusion	Vashe™ Wound Cleanser is substantially equivalent to the currently cleared and marketed Allklenz™ Cleanser, CarraKlenz Wound Cleansers, Dermacyn™ Wound Cleanser, Dermacyn™ Wound Dressing and Biopure™ MTAD™ Root Canal Cleanser



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

PuriCore Inc.  
% Mr. Dennis J. Mahoney  
Director of Quality Assurance/  
Regulatory Affairs  
508 Lapp Road  
Malvern, Pennsylvania 19355

AUG 19 2009

Re: K092232  
Trade/Device Name: Vashe® Wound Cleanser  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: August 19, 2009  
Received: August 22, 2009

Dear Mr. Mahoney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

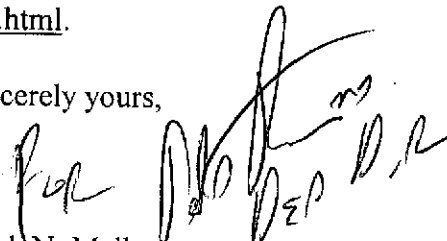
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Dennis J. Mahoney

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name. The signature is stylized with a large 'M' and 'N'.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K092232 1/1

## Attachment 2

### Indications for Use Statement

510(k) Number :

K092232

Device Name : Vashe® Wound Cleanser

#### Indications for Use :

Vashe® Wound Cleanser is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

The Vashe® Wound Cleanser is intended for used by qualified health care personnel trained in its use

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use: ☐

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDHR, Office of Device Evaluation (ODE)

David Krone for MKA  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K092232